

### **REMARKS**

A check for the fee for a five-month extension of time and for filing an RCE accompanies this response. Any fees that may be due in connection with the filing of this paper or with this application during its pendency may be charged to Deposit Account No. 06-1050. If a Petition for Extension of time is needed, this paper is to be considered such Petition.

Claims 1, 4, 6, 7, 9-27, 29-32 and 34 are pending in this application. The renumbering of claim 33 to claim 34 herein reflects the correct numbering of claims in accordance with 37 C.F.R. §1.1266. Applicant inadvertently mis-numbered this claim as claim 33 in the response filed March 30, 2004. This amendment was submitted in the previous Response After Final. It is unclear in the Advisory Action whether the amendment to correct the claim number was entered. Accordingly, it is presented herein.

The Response, mailed March 30, 2004, responsive to the Office Action mailed September 30, 2003, is incorporated in its entirety by reference herein (hereinafter referred to as "Response"), as is the Amendment after Final, mailed October 14, 2004, responsive to the Final Office Action mailed June 21, 2004 (hereinafter referred to as "Amendment after Final"). Because several arguments responsive to the Final Office Action were submitted for the first time in the Amendment after Final, Applicant is re-submitting those arguments in the instant RCE, and incorporating the Amendment after Final by reference herein, for consideration as a matter of right. Applicant respectfully requests consideration and entry of the arguments and remarks provided herein, and consideration and entry of the Amendment after Final mailed October 14, 2004.

#### **Advisory Action**

In the Advisory Action, the Examiner alleges that the Amendment after Final has been considered but does not place the application in condition for allowance because Applicant's arguments allegedly are duplicative and have been addressed in previous Office Actions. Applicant respectfully disagrees.

The Amendment after Final provides arguments further to those filed in the Response, traversing the rejections maintained in the Final Office Action on grounds of indefiniteness, lack of written description and lack of enablement. In addition, Applicant addressed rebuttals, set forth by the Examiner for the first time in the Final Office Action, of various arguments made by Applicant in the Response. Applicant's arguments addressing the

Examiner's rebuttals in the Final Office Action are not "duplicative," nor have they been addressed by the Examiner in "previous Office Actions." The Advisory Action provides no explanation why Applicant's arguments addressing the Examiner's rebuttals, which are not duplicative, fail to overcome the rejections of record.

Furthermore, in the Amendment after Final, Applicant responded to the rejections on grounds of double-patenting. Applicant also addressed the Examiner's objections regarding references that allegedly were submitted for consideration without an accompanying Information Disclosure Statement. It is respectfully submitted that neither of these issues had been addressed by Applicant in previous responses, nor has the Examiner responded to them. **Summary of Arguments made by Applicant in the Amendment after Final that have not been addressed by Examiner in the Advisory Action nor, in previous Office Actions:**

Summarized in turn below with respect to each rejection set forth in the Final Office Action are (1) the Examiner's reasons for rejection, including rebuttals of Applicant's arguments in previous responses, set forth in the Final Office Action; and (2) Applicant's remarks in the Amendment after Final addressing the Examiner's reasons for rejection, pointing to issues addressed and arguments made that are not duplicative with previous responses and have not been addressed by the Examiner in previous Office Actions. Briefly, the various sections and arguments in the Amendment after Final that are not addressed by the Examiner, are as follows:

**(I) Information Disclosure Statements:** This section addresses the Examiner's objection in the Final Office Action that references submitted by Applicant in support of arguments made in the "Response" allegedly cannot be considered because they are not provided in an Information Disclosure Statement.

In the Amendment after Final, Applicant provided reasons why the references must be considered even if they are not cited in an Information Disclosure Statement; and (2) the references nonetheless were cited in an Information Disclosure Statement or cited by the Examiner in previous Office Actions, thereby obviating the Examiner's basis for this objection. The Advisory Action fails to address the remarks made by Applicant responsive to this objection.

**(II) Indefiniteness:** This section addresses the Examiner's assertion in the Final Office Action that the claims are maintained as being indefinite because (A) the specification allegedly only recites the "properties" of a satellite artificial chromosome and not the

“essential elements” that define its metes and bounds; (B) Applicant’s remarks in the “Response” that the instant subject matter is of a pioneering nature like the telephone and the automobile and therefore cannot be described using known terms of art allegedly are not persuasive because unlike previous pioneering inventions, Applicant allegedly has not provided any working models or drawings of a satellite artificial chromosome; and (C) Applicant’s remarks in the “Response” that the term “satellite artificial chromosome” is presumptively definite based on valid issued patents allegedly are not persuasive because each case is “different” and treated on its own merits.

In the Amendment after Final, Applicant responded to the Examiner’s rebuttals by arguing and demonstrating that (A) each and every element of a satellite artificial chromosome as defined in the specification is clear from the description in the specification in light of the knowledge of those of skill in the art; (B) the application provides numerous figures and working examples demonstrating features of a satellite artificial chromosome, generation of a satellite artificial chromosome and uses of a satellite artificial chromosome; and (C) while unrelated cases may be treated on their own merit, the instant application and the applications on which the issued patents are based rely are part of the same case and rely on the same disclosure for the claimed subject matter - The Patent Office cannot denigrate the validity of issued patents and must give full faith and credit to its own findings. The Advisory Action fails to address these arguments, nor have they been addressed in previous Office Actions.

**(III) Written Description:** In the Final Office Action, the Examiner maintains the rejection of the claims for alleged lack of written description demonstrating possession of a satellite artificial chromosome, for reasons of record. In the “Response” and Amendment after Final, Applicant pointed to extensive descriptions throughout the specification of the relevant, identifying characteristics of satellite artificial chromosomes. In addition, Applicant argued that claims to a generic satellite artificial chromosome have issued based on the same disclosure that is relied on in the instant application. The Examiner has failed to address, in the Advisory Action or elsewhere, why Applicant’s arguments and demonstrations are not persuasive of possession of the claimed subject matter. Further, the Examiner has failed to address the inconsistent position taken by the Patent Office, where claims that find basis in the same disclosure can satisfy the written description requirement in one case (*i.e.*, the

issued patents, which are presumptively valid) yet fail to satisfy the written description requirement in the instant case.

**(IV) Enablement:** In the Final Office Action, the Examiner maintains the rejection of the Claims on grounds of inadequate scope of enablement, for reasons of record. In addition, the Examiner rebuts that the DECLARATION of Fabijanski filed in support of Applicant's arguments allegedly is unpersuasive because, "The stated experiments each describe the introduction of a mouse SATAC into plant protoplasts;" and none of the claims is drawn to "a SATAC comprising plant amplified vector DNA as well as heterochromatic DNA."

In the Amendment after Final, Applicant responded to the Examiner's rebuttals by arguing (1) that the demonstration of introducing a mouse satellite artificial chromosome into plant cells in fact directly addresses the issue of scope of the instant claims, by demonstrating transfer across very diverse species; and (2) the "plant amplified vector DNA as well as heterochromatic DNA" pointed to by the Examiner are in fact a satellite artificial chromosome, which is a chromosome that is predominantly heterochromatic and that can contain portions of heterologous DNA (Plant vector DNA is an example of heterologous DNA; Amplified pericentric regions are an example of heterochromatic DNA); therefore, the demonstration of a chromosome containing plant vector DNA and amplified pericentric regions is in fact a demonstration of a plant satellite artificial chromosome, commensurate in scope with the claims. Applicant has demonstrated preparation of a plant SATAC, prepared as described in the application.

Applicant also argued the inconsistency of the Patent Office issuing claims to a satellite artificial chromosome and a cell containing a satellite artificial chromosome (presumptively valid and enabled) based on disclosures that are substantially identical to those that form the basis for the instantly claimed subject matter. None of these rebuttals were submitted in previous responses, nor has the Examiner addressed them in the Advisory action or previous Office Actions.

**(V) Double-Patenting:** In the Amendment after Final, Applicant traversed the rejection on grounds of double-patenting. Specifically, Applicant requested clarification as to whether the grounds for rejection are statutory double-patenting or obviousness-type double-patenting. This request for clarification, which was made for the first time in the Amendment after Final, has not been addressed by the Examiner in the Advisory Action, nor in any previous Office Actions.

## **I. Information Disclosure Statements**

In the Final Office Action, the Examiner alleges that Applicant provided references with the "Response" that were not made of record in a PTO-1449 form and therefore failed to comply with 37 CFR 1.97.

This objection, raised by the Examiner for the first time in the Final Office Action (responsive to the previous "Response" filed by Applicant), was addressed by Applicant for the first time (i.e., non-duplicative) in the Amendment after Final and is summarized below:

First, as set forth in the MPEP §609 (III C3), there is no requirement that references submitted in support of arguments responsive to an Office Action be made of record in an Information Disclosure Statement:

To the extent that a document is submitted as evidence directed to an issue of patentability raised in an Office action, and the evidence is timely presented, applicant need not satisfy the requirements of 37 CFR 1.97 and 37 CFR 1.98 in order to have the examiner consider the information contained in the document relied on by applicant. In other words, compliance with the information disclosure rules is not a threshold requirement to have information considered when submitted by applicant to support an argument being made in a reply to an Office action.

Second, even though there is no such submission requirement, Applicant has made every effort to submit such references in Information Disclosure Statements. The Amendment after Final refers the Examiner to Information Disclosure Statements filed May 24, 2001, July 28, 2003, and March 30, 2004, which together contain all of the references discussed in the "Response," with the exception of Shen *et al.* and Avramova *et al.*, which were cited by the Examiner in Office Actions dated November 2002 and January 2004, respectively. For the Examiner's convenience, a table listing each of the references cited in the "Response," and the corresponding Information Disclosure Statement citing each reference is provided as Appendix A in the Amendment after Final. Applicant therefore respectfully submits that not only is the basis for the Examiner's objection improper, but the grounds for objection are obviated and the references must be considered.

## **II. The Rejection on grounds of Indefiniteness under 35 U.S.C. §112, second paragraph**

In the Final Office Action, Claims 1, 4, 6, 7, 9-27, and 29-32 are rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter. Specifically, the Examiner maintains that the term "satellite artificial chromosome" is unclear.

The Final Office Action further rebuts, responsive to Applicant's "Response":

- (A) That the instant application, while reciting the "properties" of a satellite artificial chromosome, does not teach the essential elements of a satellite artificial chromosome, nor the metes and bounds of a satellite artificial chromosome.
- (B) Responsive to Applicant's argument set forth in the "Response" that the term "satellite artificial chromosome" describes a heretofore unknown product, like other pioneering inventions such as the telephone and automobile, the Examiner rebuts that unlike the patent applications for the telephone and automobile, no drawings, figures or working models of satellite artificial chromosomes are provided in the instant application.
- (C) Responsive to Applicant's arguments in the "Response" that the term "satellite artificial chromosome" is presumptively definite because claims to satellite artificial chromosomes and related methods have issued in two patents, U.S. Patent Nos. 6,077,697 and 6,025,155, the Examiner alleges that the issued patents have no bearing on the instant application because each case is treated on its own merit.

The Amendment after Final addresses these rebuttals for the first time, and the Advisory Action fails to respond.

- A. "Satellite artificial chromosome" and its "essential elements" are sufficiently defined and described in the specification so that the metes and bounds of a satellite artificial chromosome are clear. Contrary to the Examiner's assertions in the Final Office Action, the specification does not "merely" describe "properties" of a satellite artificial chromosome, but clearly defines each of its elements**

In the Amendment after Final, Applicant provides reasons why the term "satellite artificial chromosome" (also referred to herein as SATAC) is described in the specification in terms of each of its "essential elements" in a manner that defines the metes and bounds of the term in accord with the requirements of 35 U.S.C. §112, second paragraph. As explained herein and in the Amendment after Final and in previous responses, the term "satellite artificial chromosome" refers to a chromosome that is predominantly heterochromatic, that is composed of repeating units of short satellite DNA, and that contains more heterochromatin than euchromatin (see, *e.g.*, page 7, lines 9-14, page 19, lines 5-7 and page 94, lines 3-21). The specification describes that a satellite artificial chromosome can contain heterologous DNA in addition to heterochromatic nucleic acid (page 19, lines 3-7). The application is directed to teaching how to make and use satellite artificial chromosomes, and includes definitional language as well as diagrammatic representations and working examples.

The specification further provides extensive descriptions of each of the terms in the definition of a satellite artificial chromosome and describes exemplary embodiments of chromosomes that fall within the definition of a satellite artificial chromosome. For example, the specification describes heterochromatin as chromatin that is unusually condensed and thought to be transcriptionally inactive (at page 17, lines 28-30). Further, the specification describes that chromosomes containing heterochromatin can be distinguished from those containing euchromatin by staining patterns as well as by differences in their gene content (see, e.g., page 17, lines 27-28). At page 21, lines 28-30, the specification defines heterologous DNA as DNA that does not occur naturally as part of the genome. Page 22, lines 2-12 of the specification provides examples of heterologous DNA that can form part of the satellite artificial chromosome. As described in great detail in the previous "Response" and Amendment after Final, each of the elements of a satellite artificial chromosome are clearly defined in the specification so that the metes and bounds of the term "satellite artificial chromosome," in light of the specification and as understood by those of skill in the art, are clear. Therefore, the Examiner's objection that the elements of a satellite artificial chromosome are unclear, is without merit.

**B. The Examiner's assertion in the Final Office Action regarding the lack of working examples and drawings of a satellite artificial chromosome in the instant application, is without merit.**

The Examiner's assertion that the satellite artificial chromosome, unlike other pioneering discoveries like the automobile and the telephone, is not supported by sufficient working examples and drawings in the specification is without merit. As noted in the Amendment after Final, Applicant has provide a new vector, a satellite artificial chromosome, for which a new name had to be coined because of its pioneering nature. The application provides numerous drawings and "working models" of a satellite artificial chromosome, each of which is described in great detail in the Amendment after Final and in the "Response." Neither the Advisory Action, nor previous Office Actions, have provided any explanation of why the drawings and working examples in the specification are deficient in describing a satellite artificial chromosome, nor how or why they are deficient relative to the drawings depicting other pioneering inventions like the telephone or automobile.

For example, the specification depicts the structures of satellite artificial chromosomes schematically in Figures 2 and 3. In particular, the formation of a megachromosome, which is a satellite artificial chromosome, is shown in Figures 2D, 2E and

2F and the structure of an exemplary megachromosome is depicted in Figures 2F and 3. These drawings were based on detailed studies of satellite artificial chromosomes (see, for example, pages 93-103), including *in situ* hybridization with satellite DNA as a probe for heterochromatic DNA and hybridization with euchromatic probes (for example, pages 94-95), Hoescht staining (for example, page 95) and FPG staining (for example, page 96) to observe the chromosome architecture within a satellite artificial chromosome. In addition, pulse field gel electrophoresis and southern hybridization were used to map satellite artificial chromosomes (for example, page 96). Cloning and sequencing of regions of satellite artificial chromosomes were employed to confirm the structure of the chromosome (for example, pages 97-98). Additionally, such satellite artificial chromosomes were observed directly by scanning electron microscopy (for example, page 97).

The specification further provides detailed descriptions of methods of making satellite artificial chromosomes, and numerous working examples that detail the formation and characterization of satellite artificial chromosomes and cells with satellite artificial chromosomes. These are described in the "Response" and Amendment after Final in great detail. In addition, "working models" of satellite artificial chromosomes are provided, for example, in Example 6, which describes three exemplary cell lines, G3D5, H1D3 and mMC21, containing satellite artificial chromosomes. The patent (U.S. Patent No. 6,077,697) claiming these cell lines has issued; therefore the cell lines are publicly available without restriction as "working models." The Examiner has failed to address, in the Advisory Action or elsewhere, how or why the drawings, and working models described in the application and further pointed out by Applicant in the "Response" and Amendment after Final are deficient.

**C. The Examiner's assertion that claims to satellite artificial chromosomes and related methods in the two issued patents, U.S. Patent Nos. 6,077,697 and 6,025,155, have no bearing on the definiteness of this term in the instant case is incorrect.**

In the Final Office Action, the Examiner rebutted Applicant's argument in the "Response" regarding the presumptive definiteness of the term "satellite artificial chromosome" based on issued claims to satellite artificial chromosomes, by arguing that the issued claims are irrelevant because "each case is treated on its own merit." In the Amendment after Final, Applicant responded by arguing that while unrelated cases may be treated on each case's own merit, the instant application and the aforementioned two issued patents are based upon the same application(s) and belong to the same family of cases.



Further, the disclosure on which the claimed subject matter is based, is the substantially the same. The instant claims find basis in U.S. application serial nos. 08/695,191, 08/682,080 and 08/629,822; the application claims priority to those applications. U.S. Patent No. 6,077,697 is based on U.S. application serial nos. 08/682,080 and 08/629,822; U.S Patent No. 6,025,155, is based on U.S. application serial nos. 08/695,191 and 08/629,822.

Accordingly, the instant claims find basis in the same disclosure(s) on which the claims in the issued patents are based. Thus, recitation of "satellite artificial chromosome" is presumptively definite. The Patent Office cannot denigrate the validity of issued patents and must give full faith and credit to its own findings. MPEP §1701. Neither the Advisory Action, nor any previous Office Action, addresses this inconsistency.

In summary, in light of the remarks above, demonstrating the extensive description and definition of the term "satellite artificial chromosome" present in the disclosure, in addition to the presumptive validity of the term based on issued claims in parent patents, Applicant respectfully requests that this rejection be withdrawn.

### **III. The Rejection under 35 U.S.C. §112, first paragraph: Written Description**

The Final Office Action maintains the rejection of claims 1, 4, 6, 7, 9-27, 29-32 and 34 under 35 U.S.C §112, first paragraph for alleged lack of written description, because it is alleged that the specification does not describe the subject matter in such a way as to convey to one skilled in the relevant art that the inventor(s) had possession of the claimed subject matter at the time the application was filed, for the reasons of record. Two reasons are provided for the rejection: A) It is alleged that because satellite artificial chromosomes and plant satellite artificial chromosomes are not disclosed with sufficient identifying characteristics to be considered to be possessed by Applicant; and B) It is alleged that there are insufficient identifying characteristics to "predictably" determine the structure and function of a satellite artificial chromosome in order to use the satellite artificial chromosome as a starting material for producing a cell that contains a satellite artificial chromosome or a plant satellite artificial chromosome and then identifying the cell containing a satellite artificial chromosome or plant satellite artificial chromosome.

In the "Response" and Amendment after Final, Applicant argued and extensively demonstrated that the application provides sufficient written description of satellite artificial

chromosomes to demonstrate Applicant's possession of satellite artificial chromosomes at the time of filing and as of the earliest priority date of the instant application.

A. The specification provides sufficient identifying characteristics of satellite artificial chromosomes, including plant satellite artificial chromosomes, to evidence Applicant's possession of the claimed subject matter as of the filing date of the instant application and as of its earliest priority date. There are numerous descriptions in the specification demonstrating that Applicant had possession of the claimed subject matter as of its earliest priority date and at the time of filing. The "Response" and Amendment after Final, incorporated by reference herein, pointed extensively to descriptions in the specification, working examples and figures depicting the claimed subject matter, all evidencing Applicant's possession of the claimed subject matter at the time of filing. Applicant respectfully submits that the Examiner has provided no reason, in the Advisory Action or previous Office Actions, explaining why such detailed description fails to provide identifying characteristics sufficient to satisfy the written description requirement.

Further, Applicant respectfully submits that the Examiner has provided no basis to doubt the veracity of the description of what is claimed. The specification describes the satellite artificial chromosomes in great detail and provides working examples. The inventors and the assignee(s) of this application had possession of the satellite artificial chromosomes, which are described in the application. A company, Chromos Molecular, Inc., was formed prior to filing the application to commercialize these products, which they have done.

Not only does the specification describe satellite artificial chromosomes in great detail, claims to satellite artificial chromosomes and related methods have issued in two patents (U.S. Patents Nos. 6,077,697 and 6,025,155) in the same family of cases, whose claims are based on the same disclosures as the instantly claimed subject matter (U.S. application serial nos. 08/695,191, 08/682,080 and 08/629,822, which provide the basis for the claims in this application and in the issued patents. Therefore, the specification clearly evidences possession of satellite artificial chromosomes as of this application's earliest priority date.

The disclosure relied on by the Examiner in alleging that the instant application fails to describe a satellite artificial chromosome, is substantially *identical* to the disclosure of the parent applications upon which the issued patents are based. The Examiner has failed to address the inconsistency of why claims based on substantially identical disclosures from the

same family of cases presumptively satisfy the written description in the issued patents but fail to satisfy the written description requirement in the instant application.

**B.** With regard to the Examiner's assertion that satellite artificial chromosomes are not described in the instant application in such a way as to "predictably" determine the structure and function of a satellite artificial chromosome, Applicant maintains that the issue of predictability goes to a determination of enablement and is not pertinent to a consideration of written description. As discussed in detail in the "Response" and the Amendment after Final, the instant application describes satellite artificial chromosomes and cells containing satellite artificial chromosomes in extensive detail so that satellite artificial chromosomes and cells containing satellite artificial chromosomes can be reproducibly and "predictably" produced and identified by one of skill in the art. The application describes methods of generating satellite artificial chromosomes of a variety of species, plant or animal, that can be introduced into any cell type. The application describes in exquisite detail the structures of satellite artificial chromosomes, including detailed descriptions of intermediate structures formed in the generation of satellite artificial chromosomes. The application also provides methods for selecting and identifying cells containing satellite artificial chromosome. These descriptions, as stated in the specification and pointed to in the "Response" and Amendment after Final, are applicable to all satellite artificial chromosomes, including plant satellite artificial chromosomes.

Again, in view of the extensive descriptions provided, Applicant respectfully submits that the Examiner has provided no basis to doubt that Applicant possessed satellite artificial chromosomes and cells containing satellite artificial chromosomes at the time filing of the application and as of the earliest priority date. The Examiner has failed to address why the detailed descriptions and working examples pointed to by Applicant in previous responses fail to demonstrate possession of the claimed subject matter. As noted previously, an Applicant need not provide a representative of everything claimed, but may show possession by providing identifying features common to all members. Applicant, by way of detailed descriptions of features, figures, working examples and exemplary satellite artificial chromosomes and cell lines, has done exactly that. Such disclosures evidence Applicant's possession of plant satellite artificial chromosomes and cells containing such chromosomes. Therefore, it is respectfully submitted that Applicant had possession of the claimed subject matter at the time the instant application was filed.

#### **IV. The Rejection under 35 U.S.C. §112, first paragraph: Enablement**

In the Final Office Action, the Examiner has maintained the rejection of Claims 1, 4, 6, 7, 9-27, 29-32 and 34 under 35 U.S.C. §112, first paragraph, on grounds of inadequate scope of enablement, for reasons of record. In particular, the Examiner maintains that while the specification provides methods for the preparation and transfer of an animal satellite artificial chromosome into a mammalian cell (human, mouse and hamster cells), there is no evidence that these methods produce a satellite artificial chromosome from any source (*e.g.*, plants) that is operable in any cell type (*e.g.*, a plant cell).

Responsive to the DECLARATION of Fabijanski filed in support of Applicant's arguments in the previous "Response," the Examiner rebuts that the DECLARATION is unpersuasive because, "The stated experiments each describe the introduction of a mouse SATAC into plant protoplasts." With respect to the experiments demonstrating the generation of a plant satellite artificial chromosome, the Examiner rebuts that the experiments show a chromosome breakage product that contained the plant amplified vector DNA as well as heterochromatic DNA, but that none of the claims is drawn to "a SATAC comprising plant amplified vector DNA as well as heterochromatic DNA."

In the Amendment after Final, Applicant addressed the rejection and the Examiner's rebuttals. Applicant argued that in addition to providing a complete and detailed analysis of the factors set forth in In re Wands in the "Response," the DECLARATION of Fabijanski, provided with the "Response," further demonstrates that by following the teachings of the application, one of skill in the art can: (1) transfer satellite artificial chromosomes across species, including very diverse species and (2) generate a plant satellite artificial chromosome and cells containing a plant satellite artificial chromosome.

Applicant then addressed the Examiner's rebuttals of the DECLARATION. In particular, Applicant argued that the demonstration of introducing a mouse satellite artificial chromosome into plant cells directly addresses the issue of scope of the instant claims, by demonstrating transfer across very diverse species. The Examiner has provided no reason linking why a demonstration that a mouse satellite artificial chromosome can be introduced into a plant cell has no bearing on scope of enablement of the instant claims. Furthermore, operability is not an issue with respect to enablement, but with respect to 35 U.S.C. 101; no rejection on that basis has been set forth.

Applicant also addressed the Examiner's rebuttal that a demonstration of a chromosome breakage product containing "plant amplified vector DNA as well as heterochromatic DNA," allegedly are not elements of the instant claims. These experiments in fact demonstrate the generation of a plant satellite artificial chromosome! A satellite artificial chromosome, as described in the instant application, is a chromosome that is predominantly heterochromatic and that can contain portions of heterologous DNA. The "plant amplified vector DNA as well as heterochromatic DNA" pointed to by the Examiner are in fact a satellite artificial chromosome that is heterochromatic and contains portions of heterologous DNA. Plant vector DNA is an example of heterologous DNA. Amplified pericentric regions are an example of heterochromatic DNA (*see* for example, page 33, line 19 to page 34, line 7 of the application describing an example of generating a satellite artificial chromosome by targeting heterochromatic DNA, such as pericentric regions of a chromosome). Thus, the DECLARATION, describing the generation of a plant satellite artificial chromosome that includes amplified vector DNA and large scale amplification of pericentric regions in plant cells, is a demonstration of the generation of plant satellite artificial chromosomes *per se* as described in the application.

Therefore, Applicant respectfully submits that the DECLARATION demonstrates that the teachings of the specification are commensurate in scope with the instant claims, which are directed to methods of producing cells with satellite artificial chromosomes, including plant satellite artificial chromosomes. These arguments, made by Applicant in the Amendment after Final responsive to the Final Office Action and not in previous responses, have not been addressed by the Examiner in the Advisory Action, nor in previous Office Actions.

In summary, the conclusions of the In re Wands analysis described in the Amendment after Final and previous responses are further supported by the DECLARATION of Fabijanski. The DECLARATION demonstrates that by following the teachings of the specification, one of skill in the art can prepare and identify plant satellite artificial chromosomes and cells with plant satellite artificial chromosomes. Additionally, the DECLARATION evidences that the teachings of the application are applicable to the transfer of satellite artificial chromosomes between diverse species and that that such satellite artificial chromosomes can be identified and stably maintained following such transfers.

Thus, the teachings of the specification are not limited by the source of the satellite artificial chromosomes, or by the cell type into which they are transferred.

Applicant further argued that the instant application is a continuation-in-part of U.S. applications serial nos. 08/695,191, 08/682,080 and 08/629,822. As noted above, two U.S. patents have issued from these applications, U.S. Patent Nos. 6,077,697 and 6,025,155, with claims to satellite artificial chromosomes, cells containing satellite artificial chromosomes and methods of making satellite artificial chromosomes. Contrary to the Examiner's assertions, these issued patents are not unrelated, but in fact, the issued patents are part of the same patent family as the instant application. The instant application claims priority to U.S. applications serial nos. 08/695,191, 08/682,080 and 08/629,822, the disclosures of which are incorporated by reference in their entirety into the instant application.

The issued patents teach and claim satellite artificial chromosomes, cells containing the chromosomes and methods of making satellite artificial chromosomes that are not limited by species. For example, claims U.S. Patent No. 6,077,097 include:

1. A method comprising:  
introducing one or more DNA fragments into a cell, wherein the DNA fragment or fragments comprise a selectable marker;  
growing the cell under selective conditions to produce cells that have incorporated the DNA fragment or fragments into their genomic DNA; and  
selecting a cell that comprises a satellite artificial chromosome.
6. A cell containing a satellite artificial chromosome.
8. An isolated substantially pure satellite artificial chromosome.
50. A cell, comprising a satellite artificial chromosome, wherein the artificial chromosome comprises multiple copies of a heterologous gene or a plurality of heterologous genes.

U.S. Patent No. 6,025,155 includes claims such as:

22. A method for producing a gene product or products comprising:  
introducing satellite artificial chromosomes comprising DNA encoding the gene or gene products into cells; and culturing the cells under conditions whereby the gene product or products are expressed.

Thus, satellite artificial chromosomes of any species and methods of making satellite artificial chromosomes of any species were enabled as of the earliest priority date of the instant application. Because an issued patent is presumptively valid, 35 U.S.C §282, claims of an issued patent are presumptively enabled. Therefore, as of the effective filing date of the instant application, satellite artificial chromosomes of any species could be made, identified

and isolated using the methods and compositions taught by U.S. Patent Nos. 6,077,097, and 6,025,155, the disclosures of which are incorporated by reference in their entirety into the instant application.

As discussed by Applicant in the Amendment after Final, the instant application is not a case that is unrelated to the applications on which the issued patents are based; rather, the claims are based on the same disclosure as the issued claims to satellite artificial chromosomes and cells containing satellite artificial chromosomes. The Examiner has failed to address, in the Advisory Action or previous Office Actions, the inconsistency by the Patent Office of issuing claims based on a presumptively enabling disclosure, while now rejecting claims for alleged lack of enablement of that same disclosure.

### **Policy Considerations**

The instant application provides broad teachings of a pioneering discovery, *i.e.* satellite artificial chromosomes, as of the application's earliest priority date. Applicant is entitled to claims that are commensurate in scope not only with what Applicant has specifically exemplified, but commensurate in scope with that which one of skill in the art could obtain by virtue of that which the Applicant has disclosed. The specification teaches the preparation and introduction of satellite artificial chromosomes that are not limited by species or cell type. The DECLARATION supports the assertion of this breadth by demonstrating that by following the teachings of the specification one of skill in the art can: (1) transfer satellite artificial chromosomes across species, even among very diverse species, by demonstrating transfer of a mouse satellite artificial chromosome to tobacco, *Arabidopsis* and rice; and (2) generate a plant satellite artificial chromosome and cells containing a plant satellite artificial chromosome.

Therefore, it would be unfair, unduly limiting and contrary to the public policy upon which the patent laws are based to require Applicant to limit the instant claims to only the exemplified satellite artificial chromosomes or to specific cell types exemplified in view of the broad teachings of the application. To limit an Applicant to claims involving the specific materials disclosed in the examples so that a competitor, seeking to avoid infringement can merely follow the disclosure and make routine substitutions "is contrary to the purpose for which the patent system exists - to promote progress in the useful arts"). See, *e.g.*, In re Goffe, 542 F.2d 801, 166 USPQ 85 (CCPA 1970).

The public purpose on which the patent law rests requires the granting of claims commensurate in scope with the invention disclosed. This requires as much the granting of broad claims on broad inventions as it does the granting of more specific claims on more specific inventions" In re Sus and Schafer, 49 CCPA 1301, 306 F.2d 494, 134 USPQ 301, at 304.

To require Applicant to further limit the claims would permit those of skill in the art to practice what is disclosed in the specification but avoid infringing claims so-limited. To permit that is simply not fair. The instant application teaches the preparation of satellite artificial chromosomes from a broad range of species and the introduction of satellite artificial chromosomes into a broad range of cells. Having done so, it is now routine for others to prepare satellite artificial chromosomes from a broad variety species and to introduce them and identify them in cells of a broad variety of species. Those of skill in the art should not be permitted to make minor modifications and avoid infringing the instant claims. Thus, given the broad teachings of the application, not limited by species of satellite artificial chromosomes or by species of cells containing satellite artificial chromosomes, Applicant is entitled to claims that reflect such broad teachings.

In light of these remarks, Applicant respectfully requests that the arguments presented in the previous "Response" and Amendment after Final as well as the DECLARATION of Fabijanski be reconsidered along with the remarks herein and that the rejection be withdrawn.

#### **V. Provisional Double Patenting Rejection**

In the Final Office Action, it is alleged that claim 11 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,077,697. It is alleged that the claims are identical.

In the Amendment after Final, Applicant traversed this rejection and requested clarification. The traversal is summarized below. Applicant respectfully submits that the traversal of the double-patenting rejection, made by Applicant for the first time in the Amendment after Final responsive to the Final Office Action, has not been addressed or clarified by the Examiner in the Advisory Action, nor in previous Office Actions.

#### **Statutory Double Patenting**

Although not explicitly stated, the Final Office Action appears to set forth a new ground of rejection, statutory double patenting. The Office Action alleges that claim 1 of U.S. Patent No. 6,077,697 and claim 11 of the instant application are identical.



As set forth in the MPEP, "In determining whether a statutory basis for a double patenting rejection exists, the question to be asked is: Is the same invention being claimed twice?" MPEP §804. If so, a statutory double patenting rejection should be made. The rejection can be overcome by amending or canceling claims such that the claims are not coextensive in scope and the identical subject matter is not claimed twice. MPEP §804, ¶8.30.

By alleging that claim 1 of U.S. Patent No. 6,077,697 and claim 11 of the instant application are identical, the Examiner appears to be issuing a new rejection in a Final Office Action. A statutory double patenting rejection has not been previously made in the instant case. New rejections, if not necessitated by amendment or submission of an Information Disclosure Statement, are not proper in a Final Office Action. MPEP §706.07(a). Therefore, if the rejection set forth in the Final Office Action is a statutory double patenting rejection, such rejection was not necessitated by amendment or submission of an Information Disclosure Statement and the finality should be withdrawn.

#### **Obviousness-type Double Patenting**

The Final Office Action states that the rejection is based upon the judicially created doctrine obvious-type double patenting. Although it is explicitly stated that the rejection is set forth under the judicially created doctrine obvious-type double patenting, the rationale states that the claims at issue are identical. As noted above, such rationale is proper for statutory double patenting, not obviousness-type double patenting. As set forth in the MPEP, "In determining whether a nonstatutory basis exists for a double patenting rejection, the first question to be asked is - does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent? If the answer is yes, then an "obviousness-type" nonstatutory double patenting rejection may be appropriate." MPEP §804. A Terminal Disclaimer can be filed to overcome an obvious-type double patenting rejection if it is appropriate. Until the Examiner clarifies the basis for the rejection, Applicant cannot address the issue.

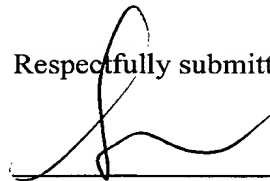
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In view of the above, reconsideration and allowance of the application are respectfully requested.

Respectfully submitted,



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Stephanie L. Seidman  
Reg. No. 33,779

Attorney Docket No. 17084-004007/402F

**Address all correspondence to:**

Stephanie L. Seidman  
Fish & Richardson P.C.  
12390 El Camino Real  
San Diego, California 92130  
Telephone: (858) 678-5070  
Facsimile: (202) 626-7796  
email: seidman@fr.com